

YEAR 9 VISIT**TABLE OF CONTENTS**

1. Overview of measurements	2
2. Working with older participants	3
3. Annual Telephone Interview, Year 9	3
4. Preparation for the cognitive vitality substudy year 9 clinic visit	4
4.1 Participant preparation	4
4.2 Cognitive vitality substudy year 9 clinic visit preparation	4
4.3 Procedure checklist and exit interview	5
4.4 Incomplete visits	5
5. Cognitive vitality substudy administration outside clinic	6
5.1 Cognitive vitality substudy in the home.....	6
5.2 Cognitive vitality substudy by telephone.....	6
6. Clinic safety	7
6.1 Background and rationale	7
6.2 Major emergencies.....	7
6.3 Minor emergencies.....	8
6.4 Emergency equipment.....	8
6.5 Emergency plans in case of fire	8
Appendix 1 Cognitive Vitality Substudy Procedure Checklist.....	10
Appendix 2 HABC Visit Scheduling	11
Appendix 3 Health ABC Year 9 Data from Prior Visits Report	12
Appendix 4 Cognitive Vitality Substudy Participants Report	13
Appendix 5 Cognitive Vitality Substudy Year 9 Pre-Visit Instructions.....	14

YEAR 9 VISIT**1. Overview of measurements**

The year 9 Health ABC visit will consist of a telephone contact for all participants and a clinic visit exclusively for participants who are part of the cognitive vitality substudy cohort.

The Annual Telephone Interview, Year 9 will include questions that have been asked in previous years; i.e., questions about medical status; physical function; physical activity and exercise; work, volunteer, and caregiving activities; appetite and weight change; smoking habits; medical conditions; fatigue; eyesight and driving; marital status and household occupancy; social network and support; health care/insurance; current address and telephone; and contact information.

All participants who were in the cognitive vitality substudy cohort during year 3 will be asked to come in to the clinic to be administered a series of cognitive vitality tests that include:

- Screener for Cognitive Vitality Substudy
- Teng Mini-mental State Examination
- Boxes Test
- Digit Copying Test
- Buschke Selective Reminding Test (SRT)
- Activity Assessment
- Cognitive Vitality Questionnaire
- Pattern Comparison Test
- Letter Comparison Test
- Simple Reaction Time Test
- Digit Digit Test
- Digit Symbol Test
- CES-D
- Digit Symbol Substitution Test

After the completion of each component of the Health ABC Cognitive Vitality Substudy, Year 9, the Procedure Checklist should be completed (see Appendix 1).

Scripts in protocols and worksheets

It is very important that examiners read the Health ABC operations manual. Scripts are included in the operations manual in order to standardize the administration of the tests given to participants in the study. Examiners should learn the standardized script that appears in the protocols and/or data collection forms.

2. Working with older participants

Participants in our research studies are NOT patients; they are very valued volunteers who deserve to interact with study staff who are always at their best. The participants are people who are willing, for very little in return, to contribute their time, energy, and honesty about their situations in the hope of making a difference. We need to do everything we can to make their time with us an enjoyable experience.

Research participants are free to refuse to have any test completed or to answer any questions that we ask. Because people who volunteer for studies tend to be generous people, refusals rarely happen. When they do occur, it is often because they do not understand what is being asked of them or why it is being requested. Take the time to explain. However, if they still refuse, respect this decision as their absolute right and move to another activity or question.

It is imperative that research participants are always treated with respect. This involves, but is not limited to, providing the necessary information to prepare them for their visit, greeting them warmly as they arrive in clinic, thanking them for their participation before the exams are started, answering any questions that they may have, thanking them again for their time and interest at the end of the visit, and not wasting their time by making them wait for long periods unnecessarily.

Dealing successfully with older research participants requires that we be sensitive to their potential needs and concerns. These needs may be related to ambulation difficulties, hearing and sight difficulties, discomforts associated with completing the clinic visit (e.g., fatigue due to their health status), competing personal difficulties (e.g., depression, an ill spouse, etc.), and the experience of being a research participant.

3. Annual Telephone Interview, Year 9

In order to determine when to schedule the Annual Telephone Interview, Year 9, check the HABC Visit Scheduling Report on the Health ABC website (Appendix 2). Ideally, the interview will be done as close to the target date as possible.

In the event that some participants may not be willing to complete the entire interview, we have identified those questions that are most important to administer; these priority questions are identified by a star (★) next to the question. If the participant is unwilling to complete the entire interview, ask the starred questions first. Once the starred questions have been asked, continue to ask the other non-starred questions, if the participant is willing. Please mark "Refused" on all questions not asked.

The Health ABC Year 9 Data from Prior Visits Report should be printed before the interview is conducted (Appendix 3). While not ideal, the telephone interview can be done in person at the clinic for those participants who come in to the clinic for the cognitive vitality substudy.

4. Preparation for the cognitive vitality substudy year 9 clinic visit

4.1 Participant preparation

In order to determine when to schedule the cognitive vitality substudy year 9 clinic visit, check the HABC Visit Scheduling Report on the Health ABC website. Ideally, the clinic visit will be done as close to the target date as possible. To see what sort of visit the participant had during year 8, look at the Cognitive Vitality Substudy Participants report (Appendix 4) on the Health ABC website.

Each participant who comes to the Health ABC clinic visit will have been told about the contents of the visit during the phone conversation to schedule the clinic visit. Reminder letters should be mailed approximately 7 to 10 days prior to the visit to emphasize the following:

- date and time of the year 9 cognitive vitality visit
- instruction to participants to take their medicines as usual
- instructions to participants that it will NOT be necessary this year to bring in their medications to the clinic
- if participants use glasses, that they bring both their reading glasses and any glasses that are used for longer distances.
- that participants who wear hearing aids should bring or wear them to the clinic.
- that participants should eat breakfast or lunch before they come in to the clinic

Ideally, reminder phone calls should be made the day before the clinic visit. Please see an example of a reminder letter in Appendix 5.

4.2 Cognitive vitality substudy year 9 clinic visit preparation

At the time of the cognitive vitality year 9 visit, the following should be available for each participant:

- A Cognitive Vitality Substudy Workbook labeled with the participant's acrostic, and Health ABC enrollment ID number; and Year 9 bubble prefill on each page
- The participant's chart. Field centers should also keep "progress notes" in the participant's chart. Progress notes may be used to record examiner comments and questions, and to document protocol problems and their resolution. Each entry should be dated and signed by the examiner recording the note.
- A Health ABC Year 9 Data from Prior Visits Report if the Annual Telephone Interview, Year 9 is being administered during the cognitive vitality substudy year 9 clinic visit.

Table 1 [below] lists all the forms that are completed during the year 9 cognitive vitality visit.

Table <u>Health ABC Cognitive Vitality Visit Year 9 Forms</u>	
<ul style="list-style-type: none">• Annual Telephone Interview, Year 9 (for all participants)• Cognitive Vitality Substudy Workbook, Year 9 (for cognitive vitality substudy cohort only)<ul style="list-style-type: none">- Cognitive Vitality Substudy Procedure Checklist- Screener for Cognitive Vitality Substudy- Teng Mini-Mental State Exam- Digit Copying Test- Buschke Selective Reminding Test (SRT)<ul style="list-style-type: none">a. Trial 1b. Total Recallc. Trial 6 LTSd. 20-30 Minute Recall- Activity Assessment- Cognitive Vitality Questionnaire- Pattern Comparison Test- Letter Comparison Test- Simple Reaction Time Test- Digit Digit Test- Digit Symbol Test- CES-D- Digit Symbol Substitution Test	

4.3 Procedure checklist and exit interview

At the end of the cognitive vitality visit, year 9, an exit interview should be performed to:

- Thank the participant. Be sure the participant knows how much we appreciate their participation.
- Answer questions. Some participants may have questions about the cognitive vitality substudy examinations.
- Make sure the Cognitive Vitality Substudy Workbook Procedure Checklist is completed, including the header information including the Health ABC Enrollment ID #; confirm that all exams and measurements were completed. Review the Cognitive Vitality Substudy Workbook and complete the Procedure Checklist appropriately. Record on the checklist whether or not a test was completed, was partially completed, whether or not the participant refused a test, or whether the test was not done for some other reason.

4.4 Incomplete visits

Very rarely, a measurement is not administered. Whenever a measurement is not administered, write the reason in the Comments section of the Cognitive Vitality Substudy Procedure

Checklist, and include a note in the progress notes in the participant's chart explaining why the measurement was not administered.

5. Cognitive vitality substudy administration outside clinic

5.1 Cognitive vitality substudy in the home

The same Cognitive Vitality Substudy Workbook that is used in the clinic should be used for home visits. All tests should be administered in the home, except for the following:

- Simply Reaction Time Test
- Digit Digit Test
- Digit Symbol Test

The tests mentioned above all require a computer and therefore, cannot be administered in the home. Please note that the Digit Symbol Substitution Test *should* be administered in the home.

When completing the Procedure Checklist for these items, please mark the "No: other reason" bubble to record why the test was not done. In addition, in the Comments column, please write in Home Visit.

5.2 Cognitive vitality substudy by telephone

The same Cognitive Vitality Substudy Workbook that is used in the clinic should be used when the tests are administered by phone. If the cognitive vitality substudy is done over the phone, only the following tests/questions can be administered:

- Selected questions (as indicated by the stars in front of the questions) in the Teng Mini-Mental State Exam (pages #3-#8)
When completing the Procedure Checklist, next to the Teng Mini-Mental State Exam (item 2), please mark the "Yes, measurement partially completed" bubble. In addition, in the Comments column, please write in Telephone Contact.
- Questions on page #15-#20 as indicated by the stars in front of the questions

For all tests that are not administered over the telephone, when completing the Procedure Checklist, please mark the "No: other reason" bubble to record why the test was not done. In addition, in the Comments column, please write in Telephone Contact.

6. Clinic safety

6.1 Background and rationale

All life threatening emergencies that occur at the Health ABC clinic, such as acute myocardial infarction, should be referred for immediate evaluation at an acute care facility, with emergency measures taken in the clinic before departure. Minor emergencies, such as hypotension or fainting, receive treatment in the clinic. Although most emergencies are of even less severe nature, Health ABC Field Center Clinics are prepared for both types.

6.2 Major emergencies

When a serious life-threatening event occurs in the clinic setting, the primary concern of the clinic staff is to implement pre-established procedures to get the participant to the nearest medical facility. It is imperative that local emergency measures be activated; in most cases, this requires calling 911. Do not take the participant to the emergency room. Let the paramedics do that. At every clinic session a physician, physician assistant, or registered nurse with certification in basic life support is on duty and physically present. Needed life support procedures should be continued until emergency care arrives or the participant is transported to a hospital.

Each Health ABC clinic has specific emergency procedures which define:

1. Who is in charge during the emergency
2. Who administers treatments
3. Who is notified
4. What action clinic staff takes
5. Which reports are filed

Each clinic has, in addition to trained personnel and emergency equipment, posted in a conspicuous place, such as the reception area, the following:

- phone number of police station
- phone number of fire stations
- phone number of ambulance services

} **CALL 911 !**

In each participant's folder, the name and phone number of their physician or usual source of health care is available on a standard Health ABC form. The home and work telephone number of the next-of-kin are also listed.

All medical emergency situations should be coordinated by a physician when present in the clinic. In the physical absence of the latter, this role should be assumed by the charge nurse or senior physician assistant. When not physically present in clinic, they are within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the head nurse and/or senior physician assistant so that the name of the responsible physician is readily accessible. However,

in no case should emergency referral or care be deferred while staff is attempting to locate a clinic doctor. All personnel should be trained to carry out their specific responsibility during an emergency. Retraining is conducted at least yearly, inclusive of any emergency drill.

All major emergencies should be documented, identifying the type of emergency and action taken. This report should be completed by the clinic coordinator and co-signed by a clinic physician and the Principal Investigator. These reports should be maintained in a central file at each field center and a copy of the report should be kept in the participant's chart.

6.3 Minor emergencies

The most common minor emergency is simple syncope (fainting) and near syncope.

In any situation in which syncope is likely, staff should verify that the participant does not look or feel faint. When the participant looks faint or feels faint the following steps should be implemented:

1. Have the person remain in the chair and sit with their head between their knees or lie down.
2. Crush an ampule of smelling salts and wave under the participant's nose for a few seconds. DO NOT place ampule directly under the nose.
3. Provide the participant with a basin and a towel when they feel nauseated.
4. Check blood pressure and pulse.
5. Have the participant stay in the chair until they feel better and their color returns. Re-check blood pressure and pulse.

If the participant continues to feel sick, recline the chair, place a cold, wet towel on the back of the person's neck, and notify the clinic nurse coordinator. If a participant faints, they should be cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house physician or nurse to assist the participant. The remaining attendant raises the participant's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the participant is breathing. When life support measures are needed, the measures outlined in the above sections are followed.

6.4 Emergency equipment


A basic first aid kit is maintained at each field center. The kit contains a reference guide of its contents, and is checked every 6 months and immediately after each use. At each Field Center, the study coordinator identifies the person responsible for this task.

6.5 Emergency plans in case of fire

1. Notify the emergency management system (911) to report the fire.
2. Close all windows and doors.
3. Escort all participants to the nearest fire exit and assemble a safe distance from the building.

4. Alert the clinic coordinator and the building supervisor of the emergency situation.

Appendix 1 Cognitive Vitality Substudy Procedure Checklist



HABC Enrollment ID #

H

Acrostic

Date Visit Completed

/
/

Month
Day
Year

Staff ID #

COGNITIVE VITALITY SUBSTUDY

Year of Visit: ● Year 9 ○ ○ ○ ○

What is your...?

First Name
M.I.
Last Name

PROCEDURE CHECKLIST

Test	Page #s	Please check if done				Comments
		Yes: measurement fully completed	Yes: measurement partially completed	No: participant refused	No: other reason	
1. Screener for Cognitive Vitality Substudy	2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2. Teng Mini-Mental State Exam	3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3. Boxes Test	9	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
4. Digit Copying Test	11	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
5. Buschke Selective Reminding Test (SRT)	13	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
a. Trial 1	14	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
b. Total Recall	14	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
c. Trial 6 LTS	14	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
d. 20-30 Minute Recall	14	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6. Activity Assessment	15	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
7. Cognitive Vitality Questionnaire	16	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8. Pattern Comparison Test	21	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
9. Letter Comparison Test	24	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
10. Simple Reaction Time Test	27	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
11. Digit Digit Test	28	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
12. Digit Symbol Test	29	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
13. CES-D	30	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
14. Digit Symbol Substitution Test	31	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Cognitive Vitality Substudy by Telephone

If the Cognitive Vitality Substudy is completed over the telephone, administer the starred "★" questions:

- Teng Mini-Mental State Exam on pages #3 through #8
- Questions on pages #15 through #20



Appendix 2 HABC Visit Scheduling

- SAMPLE -

HABC Visit Scheduling

Input data for search

Select a Month : and Year :

Select a Visit (optional)

OR

Enter a HABC ID number :

ID	Acrostic	Visit	Target Date	Window Start	Window End
HA1000	HROB	Year 9	7/15/2005	7/15/2005	9/28/2005
HA1001	AKAR	Year 9	7/15/2005	7/15/2005	9/28/2005
HA1003	JCUN	Year 9	7/15/2005	7/15/2005	9/28/2005
HA1006	TMEA	Year 9	7/15/2005	7/15/2005	9/28/2005
HA1007	JHAR	Year 9	7/15/2005	7/15/2005	9/28/2005
HA1008	APRU	Year 9	7/15/2005	7/15/2005	9/28/2005
HA1010	SGLO	Year 9	7/15/2005	7/15/2005	9/28/2005

Appendix 3 Health ABC Year 9 Data from Prior Visits Report

Participant Name:

Health ABC Enrollment ID#:

Acrostic:

1. Date of last regularly scheduled contact:
2. Missed Year 8 clinic visit?
- 2a. Reason for missed Year 8 clinic visit:
3. Type of Year 8 contact:
4. Has the participant ever had a proxy interview?
- 4a. For which contact?
5. Is participant part of the Cognitive Vitality Substudy Cohort?

If Yes, schedule Cognitive Vitality Substudy Visit

EVENTS REPORTED**The following Event Forms have been entered to date for this participant:**

Event Form Reference #	Type of Event	Date Reported	Date of Event
------------------------	---------------	---------------	---------------

Appendix 4 Cognitive Vitality Substudy Participants Report

– *SAMPLE* –

Memphis Clinic
Participants in Cognitive Vitality Substudy
As of July 17, 2005 17:32 PST

Obs	HABC ID	Type of Visit at Year 8
1	HA1001	Clinic
2	HA1003	Clinic
3	HA1006	Clinic
4	HA1008	Clinic
5	HA1010	Clinic
6	HA1013	Clinic
7	HA1017	Clinic
8	HA1021	Clinic
9	HA1029	Clinic
10	HA1033	Clinic
11	HA1035	Clinic
12	HA1040	Clinic
13	HA1049	Clinic
14	HA1050	Clinic
15	HA1052	Clinic
16	HA1058	Clinic
17	HA1069	Clinic
18	HA1071	Clinic
19	HA1073	Clinic
20	HA1077	Clinic
21	HA1078	Clinic
22	HA1079	Proxy phone
23	HA1080	Clinic

Appendix 5 Cognitive Vitality Substudy Year 9 Pre-Visit Instructions

Instructions for Year 9 Cognitive Vitality Clinic Visit

Date

Dear <Name of HABC Participant>,

Your appointment for your Health ABC Year 9 Clinic Visit has been scheduled for
_____, ____ / ____ / _____, at ____:____ a.m.
Day of Week Month Date Year Time

at XXXXXXXX, XXXXXXXX (a map is enclosed). Parking is available in the garage attached to our clinic or van transportation will be provided as prearranged.

- Take all your regular medications, as usual.
- It is NOT necessary to bring in your medications to the clinic this year.
- If you have glasses, bring both your reading glasses and any glasses that you use for longer distances.
- If you have a hearing aid, bring it with you.
- Please be sure to eat breakfast or lunch before you come to the clinic.

Thank you again for your very valuable help in this important research study! We look forward to seeing you again.

Please call XXX-XXXX if you have any questions about your visit.

6/29/05